UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/613,413 | 07/03/2003 | Matthew Sleeman | 11000.1037c5 | 9443 |

7590 06/07/2005

Gary M. Myles
SPECKMAN LAW GROUP
Suite 100
1501 Western Avenue
Seattle, WA 98101

| EXAMINER | |
|---|---|
| LI, RUIXIANG | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/613,413 | SLEEMAN ET AL. | |
| | Examiner | Art Unit | |
| | Ruixiang Li | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *72-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *72-76 and 82-86* is/are allowed.

6)☒ Claim(s) *77-81 and 87-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/823,038.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/24/04, 04/01/04*, 09/10/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence alignment*.

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. The preliminary amendment filed on September 10, 2004 has been entered in full. Claims 1-71 have been canceled. Claims 72-91 have been added. Claims 72-91 are pending and under consideration. The declaration from Dr. J. Greg Murison has also been received.

### *Information Disclosure Statement*

2.The information disclosure statement submitted on 03/24/2004, 04/01/2004, and 09/01/2004 have been considered by the Examiner and a signed copy has been attached to the office action.

### *Drawings*

3. The drawings filed on 07/03/2003 are accepted by the Examiner.

### *Objection to the Disclosure*

4. The disclosure is objected to because there is an error in reference to related patent application at page 1 of the specification. The issued U. S. Patent No. is 6,242,419, not 6,424,419. Applicant is required to correct the error.

### *Foreign Priority*

5. Acknowledgment is made of applicant's claim for foreign priority based on an application PCT/NZ00/00015, filed in New Zealand on 02/18/2000, and an application PCT/NZ03/00105, filed in New Zealand on 05/27/2003. It is noted, however, that applicant has not filed a certified copy of the application PCT/NZ03/00105 as required by 35 U.S.C. 119(b).

### *Oath or Declaration*

6. The declaration submitted on 10/19/2003 is defective because the declaration does not have the "original, first and sole/joint inventor(s) clause". It is noted that the word "first" is missing. A substitute oath or declaration in response to this action is required.

### *Claim Rejections—35 USC §112, 2nd paragraph*

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 77-81 and 87-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 77 and 87 recite a limitation, "wherein the polypeptide has the same functional properties as SEQ ID NO: 8". It is not clear what properties are referred to,

rendering the claims indefinite. Claims 78-81 and 88-91 are rejected as dependent claims from either claim 77 or claim 87.

***Claim Rejections—35 USC § 102(b)***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 77—81 and 87-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruben et al. (WO 00/24756, May 4, 2000).

Ruben et al. teach a fibroblast growth factor receptor-5 (or FGFR-5), which is 99.4% identical to SEQ ID NO: 8 of the present invention (see attached sequence alignment), and FGFR-5 fusion proteins (see, e.g., line 9 of page 1). Ruben et al. also teach treating infectious disease with FGFR-5 polypeptides by increasing the immune response, particularly increasing the proliferation and differentiation of B and/or T cells (the 3rd paragraph of page 84). Ruben et al. further teach a method of treating an individual comprising administering to such an individual a pharmaceutical composition comprising FGFR-5 polypeptides and a physiological carrier, including water and saline, and an adjuvant. Furthermore, Ruben et al. teach various routes of administering the pharmaceutical composition comprising FGFR-5, including injection (see, e.g., section of Formulation and administration at pages 94-96). Accordingly, the reference of Ruben et al. meets the limitations of claims 77—81 and 87-91.

## *Conclusion*

11. Claims 72-76 and 82-86 are allowed.

## *Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Examiner
June 2, 2005

```
FT   Peptide          238. .247
FT                    /label= antigenic
FT   Domain           240. .357
FT                    /label= extracellular
FT                    /note= "immunoglobulin domain III"
FT   Peptide          259. .262
FT                    /label= antigenic
FT   Peptide          268. .275
FT                    /label= antigenic
FT   Peptide          282. .302
FT                    /label= antigenic
FT   Peptide          307. .320
FT                    /label= antigenic
FT   Peptide          326. .334
FT                    /label= antigenic
FT   Peptide          356. .375
FT                    /label= antigenic
FT   Domain           358. .373
FT                    /label= membrane_proximal_domain
FT   Domain           374. .403
FT                    /label= transmembrane_domain
FT   Peptide          401. .435
FT                    /label= antigenic
FT   Domain           404. .504
FT                    /label= intracellular_domain
FT   Peptide          440. .443
FT                    /label= antigenic
FT   Peptide          446. .455
FT                    /label= antigenic
FT   Peptide          462. .475
FT                    /label= antigenic
FT   Peptide          483. .496
FT                    /label= antigenic
XX
PN   WO200024756-A1.
XX
PD   04-MAY-2000.
XX
PF   17-JUN-1999;   99WO-US013620.
XX
PR   23-OCT-1998;   98US-0105465P.
XX
PA   (HUMA-) HUMAN GENOME SCI INC.
XX
PI   Ruben SM,  Young PE;
XX
DR   WPI; 2000-387035/33.
DR   N-PSDB; AAA28842.
XX
PT   Nucleic acids encoding fibroblast growth factor-5 useful for the
PT   prevention, diagnosis and treatment of conditions associated with tissue
PT   repair and aberrant cell functions, e.g. cell survival and proliferation.
XX
PS   Claim 11; Fig 1A-C; 182pp; English.
XX
CC   This is the fibroblast growth factor receptor protein, FGFR-5. The FGFR-5
CC   protein and DNA may be used in the prevention, treatment and diagnosis of
CC   diseases or conditions associated with inappropriate FGFR-5 expression
CC   and activity. For example, the nucleic acids (and vectors containing
CC   them) and the FGFR-5 polypeptide may be used to treat disorders
CC   associated with increased or decreased cell survival (such as cancers
CC   (e.g. leukemia, colonic cancer, testicular cancer and follicular
CC   lymphomas), autoimmune disorders (e.g. multiple sclerosis and Crohn's
CC   disease) viral infections (e.g. herpes viruses), inflammation, graft
CC   versus host disease, acute and chronic graft rejection, ischemic injuries
CC   and atherosclerosis), activation, secretion, migration, differentiation
CC   and proliferation, diseases associated with defects in wound healing,
CC   mucositosis, defects of angiogenesis, immune dysfunction, endocrine
CC   dysfunction and insulin secretion disorders. Anti-FGFR-5 antibodies may
CC   also be used as diagnostic agents for detecting the presence of FGFR-5
CC   polypeptides in samples
XX
SQ   Sequence 504 AA;
```

```
  Query Match             99.4%;  Score 1707;  DB 3;  Length 504;
  Best Local Similarity   99.7%;  Pred. No. 1.5e-117;
  Matches  323;  Conservative    0;  Mismatches    1;  Indels    0;  Gaps    0;

Qy          1 MTPSPLLLLLLPPLLLGAFPPAAAARGPPKMADKVVPRQVARLGRTVRLQCPVEGDPPPL 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MTPSPLLLLLLPPLLLGAFPPAAAARGPPKMADKVVPRQVARLGRTVRLQCPVEGDPPPL 60

Qy         61 TMWTKDGRTIHSGWSRFRVLPQGLKVKQVEREDAGVYVCKATNGFGSLSVNYTLVVLDDI 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 TMWTKDGRTIHSGWSRFRVLPQGLKVKQVEREDAGVYVCKATNGFGSLSVNYTLVVLDDI 120

Qy        121 SPGKESLGPDSSSGGQEDPASQQWARPRFTQPSKMRRRVIARPVGSSVRLKCVASGHPRP 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 SPGKESLGPDSSSGGQEDPASQQWARPRFTQPSKMRRRVIARPVGSSVRLKCVASGHPRP 180

Qy        181 DITWMKDDQALTRPEAAEPRKKKWTLSLKNLRPEDSGKYTCRVSNRAGAINATYKVDVIQ 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 DITWMKDDQALTRPEAAEPRKKKWTLSLKNLRPEDSGKYTCRVSNRAGAINATYKVDVIQ 240

Qy        241 RTRSKPVLTGTHPVNTTVDFGGTTSFQCKVRSDVKPVIQWLKRVEYGAEGRHNSTIDVGG 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 RTRSKPVLTGTHPVNTTVDFGGTTSFQCKVRSDVKPVIQWLKRVEYGAEGRHNSTIDVGG 300

Qy        301 QKFVVLPTGDVWSRPDGSYLNKPL 324
              |||||||||||||||||||| |
Db        301 QKFVVLPTGDVWSRPDGSYLNKLL 324
```

```
RESULT 5
AAB24066
ID   AAB24066 standard; protein; 504 AA.
XX
AC   AAB24066;
XX
DT   29-JAN-2001  (first entry)
XX
DE   Human PRO943 protein sequence SEQ ID NO:29.
XX
KW   Human; tumour; diagnosis; neoplastic disease; neoplastic cell growth;
KW   proliferation; tumourigenesis; identification; cancer; cytostatic;
KW   nootropic; neuroprotective; antiinflammatory; immunosuppressive;
KW   immunostimulant; antiangiogenic; leukaemia; lymphoid malignancy;
KW   neuronal disorder; glial disorder; astrocytal disorder; angiogenic;
KW   hypothalamic disorder; glandular disorder; macrophagal disorder;
KW   epithelial disorder; stromal disorder; blastocoelic disorder;
KW   inflammatory disorder; immunologic disorder.
XX
OS   Homo sapiens.
XX
PN   WO200053755-A2.
XX
PD   14-SEP-2000.
XX
PF   06-JAN-2000; 2000WO-US000376.
XX
PR   08-MAR-1999;   99WO-US005028.
PR   02-JUN-1999;   99WO-US012252.
PR   23-JUN-1999;   99US-0141037P.
PR   07-JUL-1999;   99US-0143048P.
PR   26-JUL-1999;   99US-0145698P.
PR   30-NOV-1999;   99WO-US028313.
PR   20-DEC-1999;   99WO-US030911.
PR   05-JAN-2000; 2000WO-US000219.
XX
PA   (GETH ) GENENTECH INC.
XX
PI   Ashkenazi AJ,  Baker KP,  Goddard A,  Gurney AL,  Hillan KJ,  Roy MA;
PI   Watanabe CK,  Wood WI;
XX
DR   WPI; 2000-572270/53.
DR   N-PSDB; AAC58376.
```

```
PR   04-AUG-1998;   98US-0095321P.
PR   04-AUG-1998;   98US-0095325P.
PR   10-AUG-1998;   98US-0095916P.
PR   10-AUG-1998;   98US-0095929P.
PR   10-AUG-1998;   98US-0096012P.
PR   11-AUG-1998;   98US-0096143P.
PR   11-AUG-1998;   98US-0096146P.
PR   12-AUG-1998;   98US-0096329P.
PR   17-AUG-1998;   98US-0096757P.
PR   17-AUG-1998;   98US-0096766P.
PR   17-AUG-1998;   98US-0096768P.
PR   17-AUG-1998;   98US-0096773P.
PR   17-AUG-1998;   98US-0096791P.
PR   17-AUG-1998;   98US-0096867P.
PR   17-AUG-1998;   98US-0096891P.
PR   17-AUG-1998;   98US-0096894P.
PR   17-AUG-1998;   98US-0096895P.
PR   17-AUG-1998;   98US-0096897P.
PR   18-AUG-1998;   98US-0096949P.
PR   18-AUG-1998;   98US-0096950P.
PR   18-AUG-1998;   98US-0096959P.
PR   18-AUG-1998;   98US-0096960P.
PR   18-AUG-1998;   98US-0097022P.
PR   19-AUG-1998;   98US-0097141P.
PR   20-AUG-1998;   98US-0097218P.
PR   24-AUG-1998;   98US-0097661P.
PR   26-AUG-1998;   98US-0097951P.
PR   26-AUG-1998;   98US-0097952P.
PR   26-AUG-1998;   98US-0097954P.
PR   26-AUG-1998;   98US-0097955P.
PR   26-AUG-1998;   98US-0097971P.
PR   26-AUG-1998;   98US-0097974P.
PR   26-AUG-1998;   98US-0097978P.
PR   26-AUG-1998;   98US-0097979P.
PR   26-AUG-1998;   98US-0097986P.
PR   26-AUG-1998;   98US-0098014P.
PR   31-AUG-1998;   98US-0098525P.
PR   16-SEP-1998;   98US-0100634P.
PR   12-JAN-1999;   99US-0115565P.
XX
PA   (GETH ) GENENTECH INC.
XX
PI   Baker K,  Chen J,  Goddard A,  Gurney AL,  Smith V,  Watanabe CK;
PI   Wood WI,  Yuan J;
XX
DR   WPI; 2000-072883/06.
DR   N-PSDB; AAZ64984.
XX
PT   Membrane-bound proteins and related nucleotide sequences.
XX
PS   Claim 12; Fig 70; 822pp; English.
XX
CC   The invention provides membrane-bound PRO polypeptides and
CC   polynucleotides encoding them. The PRO sequences of the invention were
CC   identified based on extracellular domain homology screening. The PRO
CC   sequences have homology with proteins including LDL receptors, TIE
CC   ligands and various enzymes. The membrane-bound proteins and receptor
CC   molecules are useful as pharmaceutical and diagnostic agents. Receptor
CC   immunoadhesins, for instance, can be used as therapeutic agents to block
CC   receptor-ligand interactions. The membrane-bound proteins can also be
CC   employed for screening of potential peptide or small molecule inhibitors
CC   of the relevant receptor/ligand interaction. The PRO encoding sequences
CC   are useful as hybridization probes, in chromosome and gene mapping and in
CC   the generation of antisense RNA and DNA. PRO nucleic acid sequences will
CC   also be useful for the preparation of PRO polypeptides, especially by
CC   recombinant techniques
XX
SQ   Sequence 504 AA;

  Query Match             99.4%;  Score 1707;  DB 3;  Length 504;
  Best Local Similarity   99.7%;  Pred. No. 1.5e-117;
  Matches  323;  Conservative    0;  Mismatches    1;  Indels    0;  Gaps    0;

Qy          1 MTPSPLLLLLLPPLLLGAFPPAAAARGPPKMADKVVPRQVARLGRTVRLQCPVEGDPPPL 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MTPSPLLLLLLPPLLLGAFPPAAAARGPPKMADKVVPRQVARLGRTVRLQCPVEGDPPPL 60

Qy         61 TMWTKDGRTIHSGWSRFRVLPQGLKVKQVEREDAGVYVCKATNGFGSLSVNYTLVVLDDI 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 TMWTKDGRTIHSGWSRFRVLPQGLKVKQVEREDAGVYVCKATNGFGSLSVNYTLVVLDDI 120

Qy        121 SPGKESLGPDSSSGGQEDPASQQWARPRFTQPSKMRRRVIARPVGSSVRLKCVASGHPRP 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 SPGKESLGPDSSSGGQEDPASQQWARPRFTQPSKMRRRVIARPVGSSVRLKCVASGHPRP 180

Qy        181 DITWMKDDQALTRPEAAEPRKKKWTLSLKNLRPEDSGKYTCRVSNRAGAINATYKVDVIQ 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 DITWMKDDQALTRPEAAEPRKKKWTLSLKNLRPEDSGKYTCRVSNRAGAINATYKVDVIQ 240

Qy        241 RTRSKPVLTGTHPVNTTVDFGGTTSFQCKVRSDVKPVIQWLKRVEYGAEGRHNSTIDVGG 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 RTRSKPVLTGTHPVNTTVDFGGTTSFQCKVRSDVKPVIQWLKRVEYGAEGRHNSTIDVGG 300

Qy        301 QKFVVLPTGDVWSRPDGSYLNKPL 324
              |||||||||||||||||||| |
Db        301 QKFVVLPTGDVWSRPDGSYLNKLL 324


RESULT 4
AAY92864
ID   AAY92864 standard; protein; 504 AA.
XX
AC   AAY92864;
XX
DT   29-AUG-2000  (first entry)
XX
DE   Human fibroblast growth factor receptor 5.
XX
KW   FGFR-5; fibroblast growth factor receptor 5; cytostatic; anti-sclerotic;
KW   immunomodulatory; gastrointestinal; virucide; anti-inflammatory;
KW   anti-ischemic; anti-atherosclerosis; angiogenic; endocrine;
KW   anti-diabetic; gene therapy.
XX
OS   Homo sapiens.
XX
FH   Key             Location/Qualifiers
FT   Peptide         1. .24
FT                   /label= leader_sequence
FT   Peptide         23. .37
FT                   /label= antigenic
FT   Protein         25. .504
FT                   /label= mature_protein
FT   Domain          25. .117
FT                   /label= extracellular
FT                   /note= "immunoglobulin domain I"
FT   Peptide         39. .48
FT                   /label= antigenic
FT   Peptide         51. .59
FT                   /label= antigenic
FT   Peptide         62. .76
FT                   /label= antigenic
FT   Peptide         81. .97
FT                   /label= antigenic
FT   Peptide         101. .104
FT                   /label= antigenic
FT   Domain          118. .143
FT                   /label= acid_box_domain
FT   Peptide         119. .170
FT                   /label= antigenic
FT   Domain          144. .239
FT                   /label= extracellular
FT                   /note= "immunoglobulin domain II"
FT   Peptide         176. .204
FT                   /label= antigenic
FT   Peptide         209. .228
FT                   /label= antigenic
```